Texas Agricultural Experiment Station

The Texas A&M University System

Office of the Texas State Chemist

P.O. Box 3160
College Station, TX
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January 8, 1998

Dr. Bert Mitchell
Food & Drug Administration
Center for Veterinary Medicine HFV-1
7500 Standish Place
Rockville, Maryland 20855

Dear Bert:

Enclosed is a copy of my comments in response to the proposals to increase the availability of approved animal drugs for minor species and minor uses. I mailed the comments to Dr. Linda Wilmot today, January 8th.

Very truly yours,

Dr. George W. Latimer, Jr.
State Chemist

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Dockets & Management Branch (HFA-305)
Food & Drug Administration
12420 Parklawn Drive, Rm. 1-23
Rockville, MD 20857

Dear Messrs./Mesdames:

The Office of the Texas State Chemist wishes to offer written comments relating to the proposals to increase the availability of approved animal drugs for minor species and minor uses as described in the discussion draft issued by the ADAA Minor Use/Minor Species Working Group (Report CMV97132) dated 19 December 1997.

The Office of the Texas State Chemist is constituted under Section 4 TAC 141 of the Texas Agriculture Code and is charged with the responsibility of administering the Texas Feed Law. This administration includes in part the regulation of medicated feed; thus, enactment -- either legislatively or by rule -- of any of the proposals in the discussion draft directly affects the ability of the Office to perform its function under the appropriate sections of the Texas Commercial Feed Control Act.

While the discussion draft provides particular issues on which the FDA seeks comment, I prefer not to reply specifically to these proposals item by item because I believe that issues can be grouped into two sections: (1) the development of an effective and speedy approval system and (2) the ability to ensure these drugs are used appropriately.

With regard to the first, the present system, and particularly the use of NRSP-7, is a failure. In 25 years the NRSP-7 has completed 25 PMS originating from 280 animal drug requests -- one a year. Nor do the other proposals solve the problem which is one of commitment. The Agency should commit itself to a 120-day review of a standard formatted application for allowing drugs presently approved for use in major species to be used in minor species using whatever administrative or scientific techniques which would permit them to either (1) make a decision on the appropriateness of the drug or (2) say specifically what additional information is needed and then devise techniques for achieving the goal. "Temporary" approvals accompanied by a sunset provision are really unacceptable. If data say a drug is suitable for ten years, why is it not suitable for permanent use? "Temporary" approval simply permits a given firm to sell the drug under whatever circumstances are approved and leave the marketplace without ever

having completed the appropriate trials and the public would be the worse off. I do not favor the expansion of the extra label uses as prescribed by a veterinarian. Many of the animals I wish to deal with are feral -- they will never see a veterinarian -- so either the extra label use or the use of a veterinarian feed directive is entirely unrealistic.

With regard to the problem of enforcement, the FDA has completely overlooked the most appropriate mechanism for controlling the use of drugs for minor species: AAFCO and state control officials. If the FDA approved a drug for use in feeds, but required that the medicated feed must be registered in and the particular label specifically approved by the state in which it is to be regulated and sold, enforcement is simple; no extra funds, no additional congressional action would be needed. The only thing necessary would be for the FDA to assure state feed control organizations, the Association of American Feed Control Officials and industry that the Agency will actively intervene to help a state agency prosecute instances where there is abuse. The virtue of this approach is that the FDA would strengthen state programs and would have the opportunity to put into practice the partnership arrangements it has so often spoken about.

Very truly yours,

Dr. George W. Latimer, Jr.
State Chemist

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